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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,955	09/30/2003	Terence Alan Reid	7134.US.O1	5288
7590 08/05/2005			EXAMINER	
Steven F. Weinstock			NOGUEROLA, ALEXANDER STEPHAN	
Abbott Laborate	ories			
D-377/AP6D			ART UNIT	PAPER NUMBER
100 Abbott Park Road			1753	
Abbott Park, IL 60064-6050			DATE MAILED: 08/05/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	$\frac{1}{1}$				
Office Action Summary		10/674,955 Examiner	REID ET AL.  Art Unit					
		ALEX NOGUEROLA	1753					
The MAII	LING DATE of this communication			s				
Period for Reply			·					
THE MAILING C  - Extensions of time r after SIX (6) MONTI  - If the period for repl  - If NO period for repl  - Failure to reply with Any reply received by	O STATUTORY PERIOD FOR REDATE OF THIS COMMUNICATIOM may be available under the provisions of 37 CFF THS from the mailing date of this communication. It is specified above is less than thirty (30) days, a ly is specified above, the maximum statutory per in the set or extended period for reply will, by strong the Office later than three months after the madjustment. See 37 CFR 1.704(b).	DN. R 1.136(a). In no event, however, may a real. In the statutory minimum of thirtheriod will apply and will expire SIX (6) MON tatute, cause the application to become AB	reply be timely filed  ty (30) days will be considered timely.  ITHS from the mailing date of this communional to the communication to the communic	nication.				
Status								
1) Responsi	ve to communication(s) filed on _							
2a) ☐ This action	on is <b>FINAL</b> . 2b)⊠ 1	This action is non-final.						
•	application is in condition for allo	•	• •	its is				
closed in	accordance with the practice unde	er Ex parte Quayle, 1935 C.D	. 11, 453 O.G. 213.					
Disposition of Clai	ims							
4)⊠ Claim(s) <u>1</u>	1-21 is/are pending in the applicat	tion.						
4a) Of the	above claim(s) is/are with	drawn from consideration.						
5) Claim(s) _	is/are allowed.		•					
6)⊠ Claim(s) <u>1</u>	Claim(s) <u>1-21</u> is/are rejected.							
7)☐ Claim(s) _	is/are objected to.		•					
8) Claim(s) _	are subject to restriction an	id/or election requirement.						
Application Papers	5							
9)⊠ The specif	fication is objected to by the Exam	niner.	•					
· · · · · · · · · · · · · · · · · · ·	ng(s) filed on <u>30 September 2003</u>		Tobjected to by the Examiner	•				
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	ent drawing sheet(s) including the cor	• • • • • • • • • • • • • • • • • • • •	• •	121(d).				
	or declaration is objected to by the	•	• •	` '				
Priority under 35 U	J.S.C. § 119							
	dgment is made of a claim for fore	eian priority under 35 U.S.C. §	5 119(a)-(d) or (f).					
•	☐ Some * c)☐ None of:		(4) (4) (-)					
· · · <u>—</u> · ·	 tified copies of the priority docum	ents have been received.						
	tified copies of the priority docum		pplication No					
3.☐ Cop	pies of the certified copies of the p	oriority documents have been	received in this National Stage	е				
арр	olication from the International Bur	reau (PCT Rule 17.2(a)).	. •	İ				
* See the atta	ached detailed Office action for a	list of the certified copies not	received.					
Attachment(s)								
1) Notice of Reference			Summary (PTO-413)					
	rson's Patent Drawing Review (PTO-948) sure Statement(s) (PTO-1449 or PTO/SB/		s)/Mail Date  nformal Patent Application (PTO-152)					
Paper No(s)/Mail D		6) Other: <u>IDS</u>						

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#### **DETAILED ACTION**

# Specification

1. The abstract should be 150 words or less. See MPEP 608.01(b).

## Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1-10, 15-17, 20, and 21 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Hodges (WO 03/032411 A2) ("Hodges').

Addressing claim 1, Hodges discloses an electrochemical cell comprising an

insulating substrate (22), at least two conducting layers (16,18), and at least two insulating layers (26,24), wherein the at least two conducting layers are separated by at least one of the insulating layers (Figure 1).

Addressing claims 2 and 3, for the additional limitations of these claims see Figure 1.

Addressing claims 4-9, for the additional limitations of these claims see page 2:11-30. For clam 7 note that barring a contrary showing that although not used to do so the working electrodes are *capable* of being *used* to determine the presence or concentration of different analytes.

Addressing claim 10, for the additional limitation of this claim see page 13:4-8.

Addressing claims 15-17, for the additional limitations of these claims see page 11:23-30 and page 14:1-11.

Addressing claim 20, for the additional limitations of this claim let the insulating substrate be 24 and the at least two insulating layers be 22 and 26.

Addressing claim 21, for the additional limitation of this claim see Figure 1.

4. Claims 1-9, 11, 13-17, 20, 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the English language translation of Urban (WO 90/12314 A1) ("Urban").

Addressing claim 1, Urban discloses an electrochemical cell comprising an insulating substrate (5), at least two conducting layers (1,2,3), and at least two insulating layers (4,4'), wherein the at least two conducting layers are separated by at least one of the insulating layers (Figures 10-13).

Addressing claim 2, for the additional limitations of this claim see Figures 10-13

Addressing claim 3, for the additional limitations of this claim see Figures 11 and 13

Addressing claims 4, 8, and 9, for the additional limitations of these claims see page 14, second full paragraph (although this passage is in reference to Figures 4 and 5, the intended uses of the these electrodes appears to apply to all of the figures).

Addressing claims 5-7, for the additional limitations of these claims consider that they are intended uses, which barring a contrary showing, the electrodes in the electrochemical cell of Urban is capable of. The cells in Figures 10-13 comprise three electrodes: a working electrode (2), a counter electrode (3), and a reference electrode (1). However, the counter electrode is *capable* of being used as a second working

electrode to measure the concentration of the same or a different analyte as the other working electrode.

Addressing claim 11, for the additional limitations of this claim see Figures 10-13.

Addressing claim 13, for the additional limitations of this claim see Figures 10 and 11

Addressing claim 14, for the additional limitations of this claim see Figures 12 and 13. Note that the examiner is broadly construing "irregular shape" to include inferior a cell profile that with non-parallel walls and a non-monotonically changing spacing between them.

Addressing claims 15-17, for the additional limitations of these claims see the last paragraph on page 11.

Addressing claim 20, for the additional limitation of this claim see Figures 11 and 13. Let the insulating substrate instead be the insulating layer between electrodes 2 and 3, let the top insulating layer 4 and the bottom insulating layer 4 be the at least two insulating layers of claim 1.

Addressing claim 21, for the additional limitation of this claim see Figures 10-13.

5. Claims 1-13 and 15-21 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Hyland (WO 03/056319 A2) ("Hyland").

Addressing claim 1, Hyland discloses an electrochemical cell comprising an insulating substrate (bottom layer 7 in Figures 2-5 and substrate 21 in Figure 6), at least two conducting layers ((5,6,9,10,10') Also see page 12:30 – page13:2, which discloses up to ten electrodes), and at least two insulating layers (other layers 7 in Figures 2-5), wherein the at least two conducting layers are separated by at least one of the insulating layers (Figures 2-6).

Addressing claim 2, for the additional limitations of this claim see Figures 2-6 and again note page 12:30 – page13:2, which discloses up to ten electrodes.

Addressing claim 3, for the additional limitations of this claim see Figures 2 and 3 and again note page 12:30 – page13:2, which discloses up to ten electrodes.

Addressing claims 4 and 5, for the additional limitations of these claims see page 6:1-3 and page 12:20-25.

Addressing claims 6 and 7, for the additional limitations of these claims see page 13, first full paragraph.

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Addressing claims 8 and 9, for the additional limitations of these claims see page 12:1-28.

Addressing claim 10, for the additional limitation of this claim see page 12:6-8.

Addressing claim 11, for the additional limitation of this claim see Figures 5 and 6.

Addressing claim 12, for the additional limitation of this claim see page 7, first full paragraph. Let, for example, the passageway have a depth of 50  $\mu$ m, a length of 0.1 mm, and a width of 0.1 mm (square cross-section from top view). Then the volume will be 500,000  $\mu$ m<sup>3</sup>, which equals 0.0005 micro liter.

Addressing claim 13, for the additional limitation of this claim see Figures 5 and 6 and page 14, first full paragraph, which discloses a circular, or square, or rectangular cross-section from a top view.

Addressing claims 15-17, for the additional limitations of these claims see page 24:1-11.

Addressing claim 18, for the additional limitation of this claim see page 22:20-24 – page 23:5.

Addressing claim 19, for the additional limitation of this claim see page 23:10-14.

Addressing claim 20, for the additional limitation of this claim see Figure 2. Let the insulating substrate instead be the insulating layer between electrodes 6 and 9, let the insulating layer between electrodes 5 and 9 be the insulating layer of claim 1 that separates at least two conducting layers, and let the insulating layer directly above electrode 7 be the second of the at least two insulating layers of claim 1.

Addressing claim 21, for the additional limitation of this claim see Figures 2 and 3.

6. Claim 1 is rejected under 35 U.S.C. 102(a) as being clearly anticipated by Fritsch et al. (US 2003/0015422 A1) ("Fritsch").

Fritsch discloses an electrochemical cell comprising an insulating substrate (bottom layer in Figure 6), at least two conducting layers (1,3,5), and at least two insulating layers (2,4), wherein the at least two conducting layers are separated by at least one of the insulating layers (Figure 6).

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### Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35

10. Claims 12, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the English language translation of Urban (WO 90/12314 A1) ("Urban") in view of Fritsch et al. (US 2003/0015422 A1) ("Fritsch").

Addressing claim 12, Urban discloses an electrochemical cell comprising an insulating substrate (5), at least two conducting layers (1,2,3), and at least two insulating layers (4,4'), wherein the at least two conducting layers are separated by at least one of the insulating layers (Figures 10-13).

Although Urban clearly discloses small dimensions for the cell (claim 15 and page 17, last paragraph, bridging to page 18), Urban does not mention a cell volume not exceeding 1 microliter.

Fritsch discloses an electrochemical cell comprising an insulating substrate and alternating layers of conductor and insulator (see the abstract and Figure 6), which also reads on Applicants' claim 1 (see the rejection under 35 U.S.C. 102(a), above). Fritsch further discloses techniques for making a cell volume down to 0.00000849056 mircoliter. See paragraph [106], using a circular cavity with a radius of  $6.5~\mu m$  and a depth of  $8~\mu m$ .

Barring evidence to the contrary, such as unexpected results, in light of Fritsch, to reduce the electrochemical cell volume in Urban to below 1 micro liter is just scaling down the cell for a smaller expected sample volume range.

Addressing claims 18 and 19, Urban discloses an electrochemical cell.

comprising an insulating substrate (5), at least two conducting layers (1,2,3), and at least two insulating layers (4,4'), wherein the at least two conducting layers are separated by at least one of the insulating layers (Figures 10-13).

Although Urban clearly discloses small dimensions for the cell (claim 15 and page 17, last paragraph, bridging to page 18), Urban does not mention the claimed thickness ranges.

Fritsch discloses an electrochemical cell comprising an insulating substrate and alternating layers of conductor and insulator (see the abstract and Figure 6), which also reads on Applicants' claim 1 (see the rejection under 35 U.S.C. 102(a), above). Fritsch further discloses techniques an embodiment having a cavity with a depth of 8 μm through two conducting layers and two insulating layers. Thus, Fritsch discloses conducting layers and insulating layers that do not exceed 100 micrometers. See paragraph [0106].

Barring evidence to the contrary, such as unexpected results, in light of Fritsch, to have a conducing layer or an insulating layer within the claimed respective ranges is just scaling down the cell for a smaller expected sample volume range.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola Primary Examiner

AU 1753

August 2, 2005